

### **REMARKS / ARGUMENTS**

Claims 1-8 are currently pending in the application. Claims 1-8 have been rejected. Claims 1 and 4 have been amended herein. Claim 1 was amended to correct a grammatical error. Applicants have amended claim 4 to particularly point out and distinctly claim the invention, *i.e.*, to recite, *inter alia*, that the “binding compound” is a “first binding compound.” No new matter has been added by way of this amendment, nor does this amendment narrow the scope of the amended claims.

Following entry of this amendment, claims 1-8 will be pending in this application. Applicants respectfully request reconsideration of pending claims 1-8.

#### **I. Rejection Under 35 U.S.C. § 112, Second Paragraph**

The Examiner has rejected claims 1-8 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite (Office Action, page 2).

For completeness, Applicants will address each ground of rejection separately.

#### **A. Claims 1 and 4**

Claims 1 and 4 have been rejected as being indefinite for the recitation of “capture antigen.”

Applicants respectfully traverse this ground of rejection.

The specification describes the meaning of “capture antigen”:

A sample is then prepared by mixing the biological specimen with magnetic particles which are coupled to a bispecific ligand specifically reactive with an antigen on the rare cell that is different from or not found on blood cells (referred to herein as a “capture antigen”), so that other sample components may be substantially removed.

Specification, page 3, lines 21-25 (Emphasis added).

Capture antigens may be any cell surface antigen that is differentially expressed on the target cells. Preferably, capture antigens are cell surface receptors that are expressed exclusively on the target cells, or that are over expressed on the target cells relative to other cells in circulation. Magnetic particles are provided that have attached an antibody composition specific for such capture antigen. These magnetic particles are mixed with a blood sample suspected of containing the rare target cell types under conditions that allow the antibody composition to form a stable complex with capture antigens whenever present in the sample....[A] population of cells is formed that is enriched for those having the capture antigen.

Specification, page 12, lines 11-15 (Emphasis added).

Thus, Applicants submit that this claim is clear and unambiguous and that claim 1 (and claim 4) comply with all the requirements of 35 U.S.C. § 112, second paragraph.

Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

**B. Claim 4**

Claim 4 has been rejected for recitation of the phrase “combining...binding compounds, and second binding compounds.”

To more particularly point out and distinctly claim their invention, Applicants have amended claim 4, *inter alia*, to clarify that the “binding compound” is a “first binding compound,” as distinguished from the “second binding compound” recited in the claim. No new matter has been added by way of this amendment, and support can be found throughout the specification.

Thus, Applicants submit that claim 4, as amended herein, is clear and unambiguous, and complies with all the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, reconsideration and withdrawal of this ground of rejection is respectfully requested.

C. **Claims 3, 6, 7, and 8**

Claims 3,6,7, and 8 have been rejected as being indefinite for reciting “abbreviations.”

Applicants respectfully traverse this ground of rejection.

Claims 3, 6, 7, and 8 recite ErbB, PI3K, Shc, and Her1, Her2 and Her3. As the Examiner is aware, only a “reasonable degree of particularity and distinctness” is required to satisfy 35 U.S.C. § 112, second paragraph, and that “[s]ome latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire” (Manual of Patent Examining Procedure, 8<sup>th</sup> Ed., Revision 2 (May 2004) (“M.P.E.P.”) § 2173.02).

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. *See, e.g., Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000).

*Id.* (Emphasis added).

Respectfully, Applicants submit the claims are clear and unambiguous with respect to these well-known proteins, as this terminology is well known in the receptor tyrosine kinase art. Additionally, these claims, read in light of the specification, are precise, clear and

unambiguous. For example, each of these proteins is disclosed in Table II as “Exemplary RTK [receptor tyrosine kinase] Dimers and Intracellular Complexes.”

Thus, Applicants submit that this claim is clear and unambiguous and that claims 3, 6, 7, and 8 comply with all the requirements of 35 U.S.C. § 112, second paragraph.

Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

## **II. Obviousness-Type Double Patenting**

The Examiner has rejected claim 1 under the judicially created doctrine of obviousness-type double patenting over claims 1 and 11 of U.S. Patent No. 6,627,400 (“the ‘400 patent”) in view of U.S. Patent No. 6,365,362 (“Terstappen”) (Office Action, pages 2-5).

Applicants respectfully traverse this ground of rejection. However, solely in an effort to advance prosecution of this application, Applicants are submitting herewith a Terminal Disclaimer signed by an attorney of record, wherein the terminal part of any patent granted on the above-identified application that would extend beyond the expiration date of the full statutory term of the ‘400 patent.

Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

## **III. Conclusion**

In view of the foregoing remarks, Applicants respectfully submit that this application is now in condition for allowance. If a telephone interview would advance prosecution of the application, the Examiner is invited to call the undersigned at the number listed below.

Applicants are submitting this response within three months of the March 29, 2005 mail date of the Office Action. Thus, no fees are believed due in connection with this

Amendment dated June 29, 2005

Application No. 10/765,773

Page 9 of 10

Amendment. However, if there are any other fees due, please charge them to Deposit Account 50-3013. If a request for extension of time and fee are required under 37 C.F.R. § 1.136 that have not been accounted for, such an extension is requested and the fee should be charged to our Deposit Account. Also, please charge any fees underpaid or credit any fees overpaid to the same Deposit Account.

Respectfully submitted,

*Nikolaos George*  
*By: Tamara M. Pertmer*  
Tamara M. Pertmer, Ph.D. (Reg. No. 47,856)  
**JONES DAY**  
12750 High Bluff Drive, Suite 300  
San Diego, CA 92130  
(858) 314-1181

*For:* Nikolaos C. George, Ph.D. (Reg. No. 39,201)  
**JONES DAY**  
222 East 41<sup>st</sup> Street  
New York, NY 10017-6702  
(212) 326-3939